Plaintiffs' Memorandum in Opposition to Joint Motion for Summary Judgment for Failure to Prove Fault Element of Public Nuisance Claims

Ex 31 – Snider Dep. Ex. 12

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225-2927
Minority (202) 225-3641

February 15, 2018

Mr. John H. Hammergren
Chairman, President and Chief Executive Officer
McKesson Corporation
One Post Street
San Francisco, CA 94104

Dear Mr. Hammergren:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee is continuing to investigate the opioid epidemic in the U.S. that is taking 115 lives per day, according to the Centers for Disease Control and Prevention.[1]

As part of our investigation, the Committee wrote to you on May 8, 2017, regarding your distribution practices generally, and in particular with respect to West Virginia. As we mentioned in that letter, the opioid epidemic has been particularly devastating to West Virginia. For example, in 2015, West Virginia had the highest opioid overdose death rate in the nation.[2] In addition to leading to numerous deaths, the opioid crisis in West Virginia has also caused many social challenges for its residents, and has devastated its economy. Press reports indicate the epidemic is now estimated to cost West Virginia $8.8 billion per year.[3] Court filings also indicate that between 2007 and 2012, McKesson distributed 46,179,600 doses of hydrocodone and 54,304,980 doses of oxycodone[4], meaning that McKesson shipped a total of 100,484,580 doses to West Virginia during this time period.

Your response to our May 8th letter, as well as data and information the Committee

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[1] Understanding the Epidemic, Opioid Overdose, The Centers for Disease Control and Prevention, August 30, 2017, *available at* https://www.cdc.gov/drugoverdose/epidemic/index.html.
[2] Centers for Disease Control and Prevention, *Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015*, December 30, 2016, *available at* https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm.
[3] *Opioid epidemic costs WV $8.8 billion annually, study says*, Charleston Gazette-Mail (Feb. 6, 2018).
[4] *See* Amended Complaint at ¶ 12, *State of West Virginia ex rel. Patrick Morrisey et al. v. McKesson Corporation*, Civ. No. 16-C-1 (Boone County, WV Circuit Court, Jan. 21, 2016).

obtained from the Drug Enforcement Administration (DEA)[5], raise a number of additional questions, which are listed below.

I. Sav-Rite No. 1, Kermit, WV

In December 2016, the *Charleston Gazette-Mail* reported that Sav-Rite Pharmacy, located in Kermit, West Virginia, was among the top purchasers of hydrocodone in West Virginia between 2007 and 2012.[6] According to U.S. Census data, the town of Kermit had a population of 406 individuals in 2010.[7]

A. DEA data indicates that over a two-year period, McKesson shipped nearly 5 million doses of opioids to a pharmacy in a town of 406 people.

According to DEA Automation of Reports and Consolidated Orders Systems (ARCOS) data obtained by the Committee, in 2006 McKesson shipped 2,211,630 hydrocodone pills and 78,500 oxycodone pills to Strosnider Pharmacy, d/b/a Sav-Rite Pharmacy No. 1. This means that in 2006, McKesson would have shipped an average of 184,303 hydrocodone pills per month (or 6,059 hydrocodone pills per day), and 6,542 oxycodone pills per month (or 215 oxycodone pills per day) to this pharmacy. In 2006, Sav-Rite Pharmacy No. 1 was the 22nd ranked retail pharmacy in the entire country in regard to the overall number of hydrocodone pills it received.[8] Applying DEA data, it can be determined that McKesson supplied 76 percent of Sav-Rite Pharmacy No. 1's hydrocodone pills that year.

The ARCOS data further show that in the following year, 2007, McKesson shipped 2,624,680 hydrocodone pills and 40,900 oxycodone pills to Sav-Rite Pharmacy No. 1. This is equivalent to an average of 218,723 hydrocodone pills per month (or 7,191 hydrocodone pills per day), and 3,408 oxycodone pills per month (or 112 oxycodone pills per day). In that same year, other distributors shipped 1,651,160 total opioids to this pharmacy, meaning that Sav-Rite No. 1 received a total of 4,316,740 doses of opioids from all distributors in 2007.

According to market reports cited by DEA in an unrelated case, an average retail pharmacy in rural West Virginia received 22,500 dosage units of hydrocodone per month in 2008.[9] Assuming that this figure was similar in 2006 and 2007, this means that in 2006,

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[5] Data provided to the Committee pursuant to the Committee's investigatory request.
[6] *'Suspicious' drug order rules never enforced by state*, Charleston Gazette-Mail (Dec. 18, 2016), https://www.wvgazettemail.com/news/health/suspicious-drug-order-rules-never-enforced-by-state/article_3c9f1983-9044-5e97-87ff-df5ed5e55418.html.
[7] American FactFinder, *Kermit town, West Virginia* (https://factfinder.census.gov) (Census 2010 Total Population).
[8] *Big Pill Network Exposed*, The Herald-Dispatch (Apr. 1, 2009), http://www.herald-dispatch.com/news/recent_news/big-pill-network-exposed/article_8e1791fc-5162-5c36-8bae-6e76bcdb3ec9.html. The article makes reference to "the two Sav-Rite Pharmacies." However, Sav-Rite Pharmacy No. 2 was only in operation between 2008 and 2009 at which point it was forced to surrender its DEA registration. Therefore, the 2006 figures are solely attributable to Sav-Rite Pharmacy No. 1.
[9] *See In re Miami-Luken*, Order to Show Cause (Drug Enforcement Administration, Nov. 23, 2015). Presumably, even this reference rate reflected overprescribing of opioids. In 2006, CDC conducted an investigation of unintentional drug poisoning fatalities in West Virginia. *See* CDC memorandum from A. Hall, J. Logan, and R.

McKesson alone supplied Sav-Rite No. 1 with roughly eight times the amount of hydrocodone that an average retail pharmacy in rural West Virginia received in 2006, and almost ten times the amount of hydrocodone that an average retail pharmacy in rural West Virginia received in 2007.

1. When did McKesson first start distributing to Sav-Rite Pharmacy No.1? Assuming it did business with Sav-Rite prior to 2006, how much hydrocodone, listed in dosage units, did it provide to this pharmacy each year prior to 2006?

2. What was McKesson's suspicious order threshold for hydrocodone dosage units per month for Sav-Rite No. 1 in 2006? In 2007?

   a. Did these differ from the thresholds for other pharmacies in rural West Virginia? If so, by how much did they differ?

   b. Please explain how McKesson established the threshold order limit for Sav-Rite No. 1 in 2006 and in 2007.

3. In 2006, did McKesson have in place policies, procedures, or systems—such as a suspicious order monitoring system—that would have alerted it to repeated Sav-Rite orders that averaged in excess of 6,000 hydrocodone doses per day? If so, please provide all documents that detail the policies, procedures, or systems that were in effect in 2006. If no, why not?

4. In 2007, did McKesson have in place policies, procedures, or systems—such as a suspicious order monitoring system—that would have alerted it to repeated Sav-Rite orders that averaged in excess of 7,000 hydrocodone doses per day? If so, please provide all documents that detail the policies, procedures, or systems that were in effect in 2007. If no, why not?

B. <u>McKesson resumed supplying opioids to Sav-Rite after federal authorities began investigating the pharmacy, and after press accounts publicized law enforcement raids on the pharmacy.</u>

In March 2008, federal authorities began investigating Sav-Rite No. 1 and a medical complex owned by individuals associated with Sav-Rite.[10] In March 2009, authorities conducted a raid on the medical complex and on Sav-Rite.[11] This raid was publicized by, among other sources, the Huntington, West Virginia *Herald-Dispatch*, which reported that:

Toblin to D. Hamilton, "Epi-Aid Trip Report: Investigation of unintentional drug poisoning fatalities --- West Virginia, 2006," (October 12, 2007). Years later, the CDC issued opioid prescribing guidelines to address the over-prescription of opioids throughout the U.S., in part based on findings from such investigations.

[10] Verified Complaint of Forfeiture, at ¶11, *United States v. $65,806.86, More or Less, In United States Currency*, No. 2:09-cv-0944 (S.D.W. Va. Aug. 18, 2009).

[11] The Herald-Dispatch, *supra* note 8.

> In an area with a population of just a few hundred, the two Sav-Rite pharmacies received millions of dosage units of the pain-killer hydrocodone in 2006 -- enough to rank 22nd nationally in most hydrocone [sic] dosage units purchased by retail pharmacies. . . . One federal agent who investigated the pharmacies said 'prescriptions are filled at such a rate that Sav-Rite workers literally throw bags containing the drugs over a divider and onto a counter in order to keep up the pace.' The agent also noticed one cash drawer 'so full that the clerk could not get it to close properly.'[12]

The owner of Sav-Rite, James Wooley, was ultimately convicted of conspiracy to acquire or obtain controlled substances and sentenced to prison in 2012.[13]

It does not appear that McKesson shipped drugs to Sav-Rite No. 1 between 2008 and 2010. However, DEA data acquired by the Committee indicates that in 2011, McKesson again began supplying drugs to Sav-Rite No. 1.

5. Was McKesson aware of the federal investigation into Sav-Rite No. 1? If so, when and how did McKesson become aware of the federal investigation?

6. Why did McKesson stop supplying opioids to Sav-Rite No. 1 between 2008 and 2010? On what date did McKesson stop supplying opioids in the 2007-2008 time frame?

7. Why did McKesson resume sales to Sav-Rite No. 1 in 2011 and 2012?

C. <u>It is not clear what due diligence McKesson conducted before filling orders from Sav-Rite No. 1.</u>

According to a federal search warrant, "Sav-Rite Kermit was ranked 22nd in the nation among retail pharmacies with respect to purchase of Hydrocodone dosage units…[t]he average per pharmacy [2006] was 97,431."[14] Reports citing residents of Kermit and the surrounding region state that "everyone in Kermit – just about everyone in the wooded hollows of Mingo County – knew the Sav-Rite was a pill mill."[15] Press reports describe "a stampede of customers…frequent[ing] the pharmacy," so many that "[t]he town had to hire an extra police officer to handle a spike in crime and extra crews to clean up the mess the pharmacy's clientele

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[12] *Id.*
[13] Federal Bureau of Investigation, *Mingo County Pharmacist Sentenced to Prison Time for Conspiracy to Acquire Controlled Substances by Fraud* (Nov. 15, 2012) (press release).
[14] Respondent's Brief, Certified Question from the Circuit Court of Mingo County, West Virginia, *Tug Valley Pharmacy et al. v. All Plaintiffs Below in Mingo County Civil Actions*, Case Nos. 10-C-251 et al., at 9 (June 2, 2014).
[15] *America's pill-popping capital*, Salon.com (Apr. 11, 2012), https://www.salon.com/2012/04/11/americas_pill_popping_capital/.

left behind – food wrappers, cigarette boxes, beer cans, condoms and needles."[16]

8. Please provide all documents related to McKesson's due diligence files for Sav-Rite No. 1 and Sav-Rite No. 2.

II. Family Discount Pharmacy, Mount Gay-Shamrock, WV and Stollings, WV

The Charleston Gazette-Mail also identified Family Discount Pharmacy, located in Mount Gay-Shamrock, West Virginia, as being among the top purchasers of hydrocodone in West Virginia between 2007 and 2012.[17] According to DEA data, between 2006 and 2016 Family Discount Pharmacy locations in Mount Gay-Shamrock and Stollings received a total of 20,287,880 doses of hydrocodone and oxycodone from all distributors. The location in Mount Gay-Shamrock received a total of 16,591,280 pills, and the location in Stollings—approximately three miles away—received 3,696,600 pills. According to U.S. Census data, in 2010, Mount Gay-Shamrock had a population of 1,779 [18] while Stollings had a population of 316. [19]

A. According to DEA data, McKesson supplied a pharmacy in Mount Gay-Shamrock, WV, with more than six times the amount of hydrocodone that an average pharmacy in rural West Virginia would have been expected to receive.

DEA ARCOS data show that, between 2006 and 2014, McKesson supplied Family Discount Pharmacy in Mount Gay-Shamrock with 5,122,920 hydrocodone pills, and 695,100 oxycodone pills, for a total of 5,818,020 pills. However, as indicated in the table below, McKesson's distributions to the Family Discount Pharmacy in Mount Gay-Shamrock varied considerably during this time period. In 2006, McKesson supplied this pharmacy with 1,767,400 hydrocodone pills, for an average of 147,283 pills per month or 4,842 hydrocodone pills per day. In 2007, McKesson supplied the pharmacy with 1,694,800 hydrocodone pills, which is equal to an average rate of 141,233 pills per month, or 4,643 pills per day. Thereafter, McKesson supplied the pharmacy with a total of 81,900 hydrocodone pills and 8,600 oxycodone pills between 2008 and 2011. In 2013, McKesson provided this pharmacy with 986,500 hydrocodone pills, in addition to 300,100 oxycodone pills, a 193 percent increase from the year prior. This equals an average rate in 2013 of 82,208 hydrocodone pills per month or 2,703 pills per day, and 25,008 oxycodone pills per month or 822 oxycodone pills per day.

Table 1: Amount of Hydrocodone and Oxycodone McKesson Provided to Family

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[16] *Flooded with pain pills, a WV town strikes back against drug distributors*, Charleston Gazette-Mail (Jan. 31, 2017), https://www.wvgazettemail.com/news/cops_and_courts/flooded-with-pain-pills-a-wv-town-strikes-back-against/article_e0831996-f5be-5fd9-8908-049838bdf38e.html.
[17] Charleston Gazette-Mail, *supra* note 6.
[18] American FactFinder, *Mount Gay-Shamrock CDP, West Virginia* (https://factfinder.census.gov) (Census 2010 Total Population).
[19] American FactFinder, *Stollings CDP, West Virginia* (https://factfinder.census.gov) (Census 2010 Total Population).

Discount Pharmacy in Mount Gay-Shamrock, WV

Year	Total Pills
2006	1,863,900
2007	1,818,900
2008	0
2009	0
2010	90,500
2011	0
2012	439,000
2013	1,286,600
2014	319,120
Total	**5,818,020**

Source: DEA data provided to the Committee.

DEA data show that McKesson also supplied hydrocodone to Family Discount Pharmacy of Stollings. According to DEA data, between 2006 and 2016, McKesson provided Family Discount Pharmacy of Stollings with 2,102,880 hydrocodone pills, and 272,580 oxycodone pills, for a total of 2,375,460 pills. McKesson supplied the pharmacy with 272,200 hydrocodone pills in 2006, and 286,100 hydrocodone pills in 2007. In 2013, McKesson supplied this location with 317,700 hydrocodone pills.

As noted above, market reports cited by DEA in an unrelated case suggest that an average retail pharmacy in rural West Virginia received 22,500 dosage units of hydrocodone per month in 2008.[20] Assuming that this figure was similar in 2006 and 2007, this means that McKesson supplied Family Discount Pharmacy of Mount Gay-Shamrock with over six times the amount of hydrocodone that an average pharmacy in rural West Virginia would have received in each of those two years.

According to DEA, these market reports further indicate that in 2013, a retail pharmacy in rural West Virginia on average received approximately 13,500 dosage units of hydrocodone per month. This means that in 2013, McKesson apparently supplied Family Discount of Mt. Gay-Shamrock with six times the amount of hydrocodone that an average pharmacy in rural West Virginia received in that year. Furthermore, these market reports indicate that an average retail pharmacy in rural West Virginia received approximately 4,500 dosage units of oxycodone per month in 2014. Assuming that this figure was similar in 2013, this means that McKesson supplied Family Discount of Mt. Gay-Shamrock with more than five times the amount of oxycodone that an average retail pharmacy in rural West Virginia would have received.

When shipments to both Family Discount Pharmacies are combined, McKesson supplied these two pharmacies with a total of 2,039,600 hydrocodone pills in 2006 and 1,980,900

[20] *See In re Miami-Luken*, Order to Show Cause (Drug Enforcement Administration, Nov. 23, 2015).

hydrocodone pills in 2007. In 2013, McKesson supplied these pharmacies with 1,304,200 hydrocodone pills.

9. What was McKesson's suspicious order threshold for hydrocodone dosage units per month for Family Discount Pharmacy Mount Gay-Shamrock for each year between 2006 and 2016?

    a. Please provide all documents related to McKesson's due diligence files for Family Discount Pharmacy of Mount Gay-Shamrock.

    b. Please provide the reason(s) for any cessation and resumption of hydrocodone and oxycodone pill distributions from McKesson to the Family Discount Pharmacy in Mount Gay-Shamrock for the years between 2006 and 2016.

10. What was McKesson's suspicious order threshold for hydrocodone dosage units per month for Family Discount Pharmacy of Stollings for each year between 2006 and 2016?

    a. Please provide all documents related to McKesson's due diligence files for Family Discount Pharmacy of Stollings.

11. In the years where it appears that McKesson provided the Family Discount Pharmacy in Mount Gay-Shamrock with zero hydrocodone and oxycodone pills, why did McKesson continue to distribute these pills to the Family Discount Pharmacy in Stollings?

12. When conducting customer due diligence or assessing whether a particular customer's order qualifies as suspicious, does McKesson assess the customer's orders relative to orders placed by other pharmacies within a particular geographic range? Was this McKesson's practice between 2006 and 2014?

III. McKesson's Suspicious Order Monitoring System

A. In January 2017, McKesson admitted that it had failed to identify suspicious orders between 2009 and 2017.

In May 2008, McKesson entered into a Settlement Agreement and Release with DEA that resulted in a $13.25 million civil penalty related to allegations that McKesson failed to report suspicious orders as required under the Controlled Substances Act.[21] That same year McKesson

[21] Press Release, U.S. Dep't of Justice, McKesson Corporation Agrees to Pay More than $13 Million to Settle Claims that it Failed to Report Suspicious Sales of Prescription Medications (May 2, 2008) https://www.justice.gov/archive/opa/pr/2008/May/08-opa-374.html.

launched its Controlled Substance Monitoring Program (CSMP), according to press reports.[22] Notwithstanding the 2008 settlement and the launch of the CSMP, in January 2017, McKesson reached a second Settlement Agreement and Release with DEA related to suspicious order reporting. In that Settlement Agreement, McKesson agreed to pay a record $150 million civil penalty and acknowledged that "at various times" between 2009 and January 2017, "it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious" based on guidance provided by DEA.[23]

However, McKesson's response to the Committee's May 8, 2017 letter seems to contradict that acknowledgment. The Committee's letter asked whether McKesson has a monitoring system in place to detect unusual or suspicious patterns or quantities of opioid orders. In response, McKesson stated that it "has had a Controlled Substances Monitoring Program ('CSMP') in place for many years and it has evolved over time."[24]

13. What system did McKesson have in place to monitor controlled substances purchases prior to 2008?

14. Was your Suspicious Order Monitoring Program (or any predecessor program) in place in each year between 2006 and 2017?

    a. Please provide any documents or manual outlining your Suspicious Order Monitoring Program, including but not limited to your CSMP Operating Manual, for each of these years.

    b. Please provide any other guidance provided to McKesson employees or contractors related to the Suspicious Order Monitoring Program in each of these years.

    c. Given the 2008 settlement and the 2008 launch of its CSMP, why did McKesson still fail to warn DEA about the large number of suspicious orders of opioids it had shipped to certain parts of the country, including West Virginia, according to the DOJ?[25]

    d. The U.S. government's investigation developed evidence that, even after designing a compliance program after the 2008 settlement, McKesson did not fully implement or adhere to its own program.[26] In the January 2017 Settlement

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[22] *As America's Opioid Crisis Spirals, Giant Drug Distributor McKesson is Feeling the Pain*, Fortune (June 13, 2017), http://fortune.com/2017/06/13/fortune-500-mckesson-opioid-epidemic/.
[23] *In re McKesson*, Settlement Agreement and Release at ¶ IV.A (Jan. 17, 2017).
[24] Letter from Geoffrey E. Hobart, Outside Counsel for McKesson Corporation, to Chairman Greg Walden and Ranking Member Frank Pallone Jr., H. Comm. on Energy and Commerce (June 8, 2017).
[25] *In re McKesson*, Settlement Agreement and Release at ¶ III (D) (Jan. 17, 2017).
[26] To support this assertion and to provide context, two distribution centers in Landover, Maryland and Washington Courthouse, Ohio were identified by McKesson in its response to this Committee as distribution centers that served

Agreement, McKesson admitted that it failed to report suspicious orders between 2009 and 2017.

i. Has McKesson conducted internal investigations to determine the cause of this failure to report? If so, please provide documents that detail the findings of any internal investigation. If not, why not?

ii. Has McKesson investigated the effectiveness of its CSMP for each year between 2009 and 2017? If so, please provide McKesson's findings. If not, why not?

iii. Did McKesson fully implement its CSMP in each of these years? If the CSMP was not fully implemented in any year between 2009 and 2017, why not?

iv. If McKesson staff failed to adhere to the McKesson CSMP standards for each year between 2009 and 2017, has McKesson investigated the reason that this was the case? If so, what were the reasons for its employees' failure to follow the CSMP standards?

B. News reports allege that McKesson failed to file any suspicious order reports with the West Virginia Board of Pharmacy between 2001 and March 2015.

According to news reports, McKesson failed to submit any suspicious order reports to the West Virginia Board of Pharmacy between 2001 and March 2015.[27]

15. Does McKesson currently file all suspicious order reports with both DEA and the West Virginia Board of Pharmacy?

    a. If so, for how long has this been McKesson's practice?

    b. If not, why not?

16. Please provide the Committee with all suspicious order reports related to orders placed by West Virginia pharmacies that McKesson filed with DEA between 2006

West Virginia. According to the January 2017 settlement, these centers and others failed to maintain effective controls against diversion. Further, according to a 2017 Fortune Magazine article, a DEA investigator for the Washington field office found that there had been no or little suspicious orders reported by McKesson in her district. This article further asserts that following a July 2011 DEA request for customer files for 20 or so suspect pharmacies, the McKesson Landover distribution center filed 318 suspicious orders in a short period of time with DEA that covered the previous months and weeks. *See As America's Opioid Crisis Spirals, Giant Drug Distributor McKesson is Feeling the Pain*, Fortune (June 13, 2017), http://fortune.com/2017/06/13/fortune-500-mckesson-opioid-epidemic/.

[27] Charleston Gazette-Mail, *supra* note 6.

and 2017.

17. Please provide the Committee with all suspicious order reports related to orders placed by West Virginia pharmacies that McKesson filed with the West Virginia Board of Pharmacy between 2006 and 2017.

18. Please provide copies of all hydrocodone or oxycodone orders placed by West Virginia pharmacies between 2006 and 2017 that McKesson refused to ship.

19. Please provide copies of all hydrocodone or oxycodone orders placed by West Virginia pharmacies between 2006 and 2017 that exceeded the monthly threshold set by McKesson.

C. DEA communications in 2006 and 2007 advised drug distributors of their obligation to develop a system to monitor suspicious orders.

Since 2006, DEA has written at least three letters to wholesale drug distributors regarding their compliance obligations under the Controlled Substances Act. First, on September 27, 2006, DEA informed distributors that "the abuse (nonmedical use) of controlled prescription drugs is a serious and growing health problem in this country."[28] The letter then reminded distributors of their duty to "design and operate a system to disclose…suspicious orders of controlled substances," and noted that "[s]uspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[29]

That letter also reminded distributors that "a distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to the suspicious circumstances," but must "exercise due care in confirming the legitimacy of all orders prior to filling." Finally, the letter provided a list of possible indications that an order created a risk of diversion.

On February 7, 2007, DEA again wrote to all to distributors. DEA provided a list of additional "Circumstances That Might Be Indicative of Diversion," such as a pharmacy "[o]rdering a limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medications ordered," and offered a list of questions that a distributor should ask a pharmacy before filling orders from that pharmacy. Suggested questions included, for example, whether a limited number of practitioners were responsible for writing a disproportionate share of the prescriptions for controlled substances being filled by the pharmacy, and what percentage of the pharmacy's business controlled substance dispensing

[28] Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control to DEA Registrants (Sept. 27, 2006).
[29] *Id.*

constituted.[30]

On December 27, 2007, DEA sent a third letter to all registered distributors. This letter advised distributors that:

> [I]f an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a 'normal pattern' to develop over time before determining where a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry.[31]

20. Did McKesson receive the September 27, 2006 letter from DEA? If so, please describe what actions McKesson took in response to this letter with regards to the pharmacies in West Virginia.

21. Did McKesson receive the February 7, 2007 letter from DEA? If so, please describe what actions McKesson took in response to this letter with regards to the pharmacies in West Virginia.

22. Did McKesson receive the December 27, 2007 letter from DEA? If so, please describe what actions McKesson took in response to this letter with regards to the pharmacies in West Virginia.

D. Court documents allege that McKesson employees informed McKesson management as early as 2008 that McKesson's Controlled Substance Monitoring Program needed improvement.

A Verified Shareholder Derivative Complaint filed against McKesson, certain McKesson executives, and McKesson's Board of Directors in October 2017 alleges that on October 22, 2008, a McKesson employee made a presentation to McKesson's Audit Committee entitled "Internal Audit Report Second Quarter FY 2009." According to the Complaint, this report assessed McKesson's CSMP as "Needs Improvement." Specifically, the Complaint alleges, this report stated that McKesson's CSMP had failed to assign some customers thresholds "to flag large shipments of controlled substances for review;" that "[d]ocumentation evidencing new

[30] Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control to DEA Registrants (Feb. 7, 2007).
[31] Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control to DEA Registrants (Dec. 27, 2007).

customer due diligence was incomplete;" that "documentation supporting the company's decision to change thresholds for existing customers was also incomplete;" and that there were "opportunities to enhance the Standard Operating Procedures."[32]

The complaint also alleges that on July 23, 2008, a McKesson vice president made a presentation to the Board of Directors which highlighted concerns about suspicious order reporting.[33]

This Complaint therefore suggests that as early as 2008, McKesson executives and its Board of Directors were on notice of potential deficiencies in McKesson's CSMP.

23. Please provide the October 22, 2008 Report entitled "Internal Audit Report Second Quarter FY 2009."

24. Please provide minutes from the July 23, 2008 Board meeting, and any documentation related to the Public Policy Update presentation made at that meeting.

25. Please provide minutes from all McKesson Board meetings held between 2006 and 2017.

26. Please provide minutes from all McKesson audit committee meetings held between 2006 and 2017.

27. Please provide the minutes from any other McKesson committee meeting at which the distribution of opioids to West Virginia was addressed

IV. Additional Requests

28. Please provide all documents related to McKesson's due diligence files for the following pharmacies: Westside Pharmacy, located in Oceana, West Virginia; Hurley Drug Company, located in Williamson, West Virginia; and Tug Valley Pharmacy, located in Williamson, West Virginia.

29. Please provide a list of McKesson's ten largest pharmacy customers in West Virginia, based upon hydrocodone and oxycodone dosage units, between 2006 and 2017.

    a. For each of these ten largest pharmacy customers, please provide the total dosage units of hydrocodone and total dosage units of oxycodone that McKesson distributed to each pharmacy in each year from 2006 to 2017.

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[32] Verified Shareholder Derivative Complaint, *Steinberg v. Bryant et al.*, Case No. 2017-0736-SG, at ¶¶ 136-37 (Del. Ch. Oct. 17, 2017).
[33] *Id.* at ¶ 149.

30. Please provide a list of all West Virginia pharmacies McKesson terminated business relationships with since January 1, 2006, and the date of termination. Please describe the reason for the termination and provide copies of any documents or communication related to any pharmacy termination.

31. For each year between 2006-2017, please provide the five states with the highest number of suspicious orders reported by your company to DEA.

32. Did McKesson ever purchase market reports from IMS Health as part of the company's new customer due diligence? If so, in what years did McKesson purchase IMS Health market reports and what specific types of reports did it purchase? If not, were market reports purchased from other sources? If McKesson purchased third party reports or other data to use in its evaluation of existing and potential pharmacy customers from January 1, 2006 until present, please provide the third party vendor as well as the specific types of reports or data McKesson utilized.

33. Please provide copies of any dashboards and reports since January 1, 2006 of aggregated purchase data by West Virginia customers that McKesson used to identify concerning trends in purchases potentially missed in the review of individual flagged orders.

34. Since January 1, 2006, did McKesson take any personnel actions for any reason related to the inadequate performance of DEA compliance responsibilities? If so, please provide the details of these personnel actions, including the name and position of the employee, date of the action, reason for the action, and all documents related to the personnel action.

Please provide the Committee with the requested information and documents by March 19, 2018.

An attachment to this letter provides additional information about responding to the Committee's request. If you have any questions, please contact Alan Slobodin, Brittany Havens or Christopher Santini of the Majority staff at (202) 225-2927 or Christina Calce or Kevin McAloon of the Minority staff at (202) 225-3641. Thank you for your prompt attention to this matter.

Sincerely,

Greg Walden
Chairman

Frank Pallone, Jr.
Ranking Member

Gregg Harper
Chairman
Subcommittee on Oversight
and Investigations

Diana DeGette
Ranking Member
Subcommittee on Oversight
and Investigations

David B. McKinley
Member of Congress

Attachment